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LEARNING OBJECTIVES

To explain:

- *the variety of sterilization processes used to sterilize medical devices and relevant standards.*
- *the approaches used to validate and routinely control sterilization processes.*
- *how CIs are categorized into different types.*
- *how CIs can be used in validating and routinely monitoring VH_2O_2 sterilization processes.*
- *the results of some new studies examining the performance of VH_2O_2 CIs.*

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SELF-STUDY SERIES

Current evidence

Monitoring vaporized hydrogen peroxide sterilization processes using chemical indicators

by Dr. Brian Kirk

Sterile single-use and reusable medical devices must be sterilized by a validated sterilization process.[1,2] There are many microbicidal agents and figure 1 shows some which have been used in sterilization processes using physical methods or chemical agents.

Physical methods include hot and cold processes. Hot processes use high pressure steam in an autoclave or dry heat in an oven. Cold processes employ ionizing radiation and are used at an industrial scale for bulk sterilization of single-use devices.

Chemical sterilization methods include those which use alkylating chemicals such as ethylene oxide (EO), formaldehyde and glutaraldehyde. Chemical sterilization also uses oxidizing agents such as hydrogen peroxide vapor, chlorine dioxide, peracetic acid and ozone gas. Many of the chemical methods operate at low temperatures (*ca*<80°C) and are used for small scale sterilization in hospitals and some, e.g. EO, in industry. In hospitals >90 percent of theatre sets are processed using steam sterilization, however there is a need for low temperature processes for instruments which cannot withstand high temperatures, e.g. flexible endoscopes. The three most popular low temperature methods used in hospitals would be EO, low temperature steam with formaldehyde (in Europe) and vaporized hydrogen peroxide (VH_2O_2).

Validation and routine control of sterilization processes

All processes used to sterilize medical devices must be validated. Validation involves proving that what we want is what we get; sterility being one such attribute. Validation involves three steps. The first is installation qualification (IQ), and this involves checking the physical status of equipment installed in the hospital, including supplied services, to make sure they are correct. The second is operational qualification (OQ) and this involves operating the sterilizer, often empty or using standardised test loads, to make sure the equipment runs correctly. The final step is performance qualification (PQ) involving tests carried out to ensure the sterilizer can process loads that the hospital wishes to sterilize.

Sterilization Process Covered (following 14937 format)	International Standard	AAMI Standard (Hospitals)
Generic Standard for any Process	EN ISO 14937	N/A-I
Moist Heat (Steam)	EN ISO 17665	ST 79
Ethylene Oxide Gas	EN ISO 11135	ST 41
Irradiation	EN ISO 11137	N/A-I
Low Temp Steam with Formaldehyde	EN ISO 25424	N/A
Dry Heat	EN ISO 20857	N/A-I
Vaporized Hydrogen Peroxide	EN ISO 22441 [a]	ST 58

Table 1: International standards for the validation and routine control of various sterilization processes used in industry and hospitals and their ANSI/AAMI equivalents for hospital sterilization. N/A-I indicates a standard for industrial sterilization exists.

aEN ISO 22441 is in development.

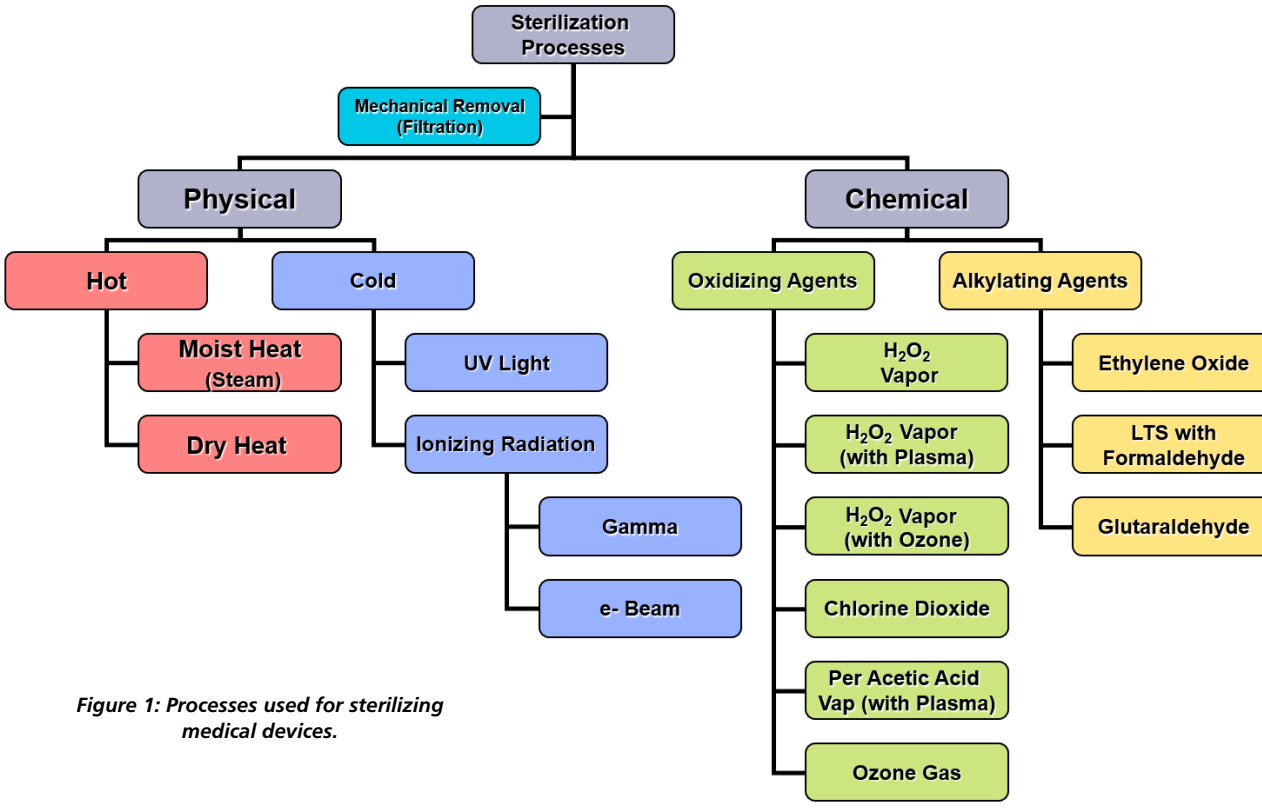

Figure 1: Processes used for sterilizing medical devices.

There are international standards describing the validation of a number of sterilization processes. These are shown in table 1 along with U.S. national equivalents. It is worth noting that there is no internationally agreed standard for validating VH_2O_2 processes; these are in development, so in the absence of a specific process standard, EN ISO 14937 applies.

In hospitals, IQ and OQ are normally undertaken by the sterilizer manufacturer or supplier and will form part the commissioning process of new equipment at the site of use. PQ is a site-specific exercise. Medical device manufacturers must provide re-processing instructions including the sterilization processes to be used. During PQ, hospitals might rely on these instructions or they may carry out some practical assessment of performance using a variety of monitoring tools.

Having validated our process, we must then ensure routine monitoring takes place to make sure the sterilization process remains efficacious, and a number of tools can be used for this purpose.

Routine monitoring of VH_2O_2 sterilization

Any sterilization process will have certain characteristics which contribute to microbial kill. These are called the "process variables." For VH_2O_2 sterilization, the process variables are the temperature and time of exposure at a specified concentration of VH_2O_2. In order to ensure every sterilization process has been effective, the process variables must be routinely monitored, and there are three basic methods for achieving this. Physical Indicators (PIs) employing instruments which measure a process variable. For a VH_2O_2 process, temperature and time are easily measured. VH_2O_2 chamber concentration can also be measured using UV light spectroscopy. PIs only provide information for one process variable, so a combination are required to get a full process picture. PIs provide no information about what is happening inside the packs being sterilized.

Biological Indicators (BIs)[3] are a preparation of a living microorganism, usually a bacterial spore, which has high resistance to, but is inactivated by, an effective process. BIs react to all of the process variables.

Chemical indicators (CIs)[4] are mixtures of chemicals which, when exposed to specified process variables (called their stated values; SVs) will change color. For example, a CIs SVs may be 2.3mg/L VH_2O_2 at 50°C for 360 seconds exposure. When exposed to these conditions the indicator must change color, indicating a pass. The manufacturer must declare the SVs in the instructions or print them on the CI.

The international standard EN ISO 11140-1[4] specifies the performance requirements for six different types of CI. These are shown in table 2 along with their uses. Types 4, 5 and 6 are for placement inside sterile packs, as required by some guidance documents.[5] They prove particularly useful for the end user who, as part of their practices, are required to check every pack to ensure external and internal indicators have given a correct response.[6] EN ISO 11140-1 does not provide requirements for types 5 and 6 VH_2O_2 CIs.

Chemical indicators for monitoring VH_2O_2 sterilization

The exposure conditions under which a type 1 CI should show a pass result (its endpoint) and a fail result are stated in EN ISO 11140-1. For a type 4 CI, the exposure conditions which give rise to a pass response (SVs) will be specified by the manufacturer ideally having some relationship to the sterilization process being

Self-Study Test Answers: 1. A, 2. C, 3. A, 4. B, 5. C, 6. B, 7. B, 8. A, 9. B, 10. B

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CI Type	Description	Use
1	Process Indicator	Used to show exposure to a process, no information provided about the quality of the process. Valuable for differentiating processed from unprocessed packs.
2	Specific Test Indicator	Used in specific tests described in equipment and process standards, e.g. Bowie and Dick Test.
3	Single Variable Indicator	Responds to one of the specified process variables e.g. temperature.
4	Multivariable Indicators	Respond to two or more of the specified process variables.
5	Integrating Indicators	Respond to all of the process variables for a given sterilization process in a manner which mimics the response expected from an equivalent biological indicator. Also provide a result which directly relates to the minimum conditions required to achieve sterilization in any given process standard (see table 1).
6	Emulating Indicators	Respond to all of the process variables for a given sterilization process providing a result equivalent to the minimum sterilization conditions specified in a process standard (see table 1).

Table 2: The types of chemical indicators specified in international standard EN ISO 11140-1.

monitored. The standard also specifies the test conditions under which a fail response should be observed and these are related to a specified reduction in each of the SVs. Table 3 shows the exposure conditions for a pass and fail response for types 1 and 4 VH_2O_2 CIs. In the example the SVs for the type 4 CI are the same as for the type 1, and the table then illustrates the test conditions required for the CI to show a fail response. It should be clear from the information shown that a type 4 CI will have greater sensitivity towards process failures.

Recent studies examining the performance of VH_2O_2 CIs

Two studies have recently been published examining the performance of some types 1 and 4 CIs. The first study[7] examined the performance of eight CIs for VH_2O_2 sterilization processes to give a pass or fail result when tested according to the methods in EN ISO 11140-1 and also to detect changes in the individual process variables time, temperature and VH_2O_2 concentration.

When tested according to the methods described in EN ISO 11140-1, it was found that two of the type 1 CIs showed appropriate pass and fail results. Another type 1 CI gave all passes and one all fails. Two of the type 4 CIs gave appropriate pass and fail results. Another type 4 showed slight differences in color in pass or fail tests and another type 4 gave the same pass color in all tests.

In the second study[8] the same CIs were tested in two sterile processing departments in US hospitals in order to examine their performance when placed in four different model loads, then processed in sterilization cycles which were recommended, and then when operated with unsuitable overweight loads or incorrectly selected sterilization processes. The ability to detect differences in sterilizing conditions within individual packs was also evaluated.

The results indicated that not all of the CIs were able to indicate if a VH_2O_2 sterilizer had not been used according to recommendations. Of the eight CIs tested, four were able to indicate the use of an incorrect loading configuration or use of an incorrect sterilization process. Two of these four were also capable of indicating non-uniformity of sterilizing conditions within individual model load packs. The results of these studies confirm the importance of using a range of monitoring systems, rather than relying on one, the information from which add to the overall assurance of process efficacy and load sterility.

Use of CIs during performance qualification

Unlike steam sterilization, which provides a high overkill, and wide utility, VH_2O_2 processes are designed for a specified range of instruments and loads. It is vital that manufacturers' recommendations are carefully followed. Failure to do so has potential implications for the sterility assurance associated with a load and indicates the importance of conducting PQ studies when introducing new devices, sterile barrier systems or accessories into the work flow in order to detect incompatibilities and potential processing problems, but also to establish the area of the pack that creates the greatest challenge to sterilant penetration, thereby informing the position of placement for routine monitoring. In hospitals it can be difficult for practitioners to carry out PQ using independent PIs since introducing sensors into the sterilizer chamber require specialist expertise. Free-standing temperature loggers, which are activated and then placed into the chamber, are available, however these can be expensive. However, PQ can still be performed using CIs and BIs. The use of CIs within instrument sets can potentially detect process problems when conducting PQ studies to ensure a new load is compatible with the intended sterilization cycle. PQ of VH_2O_2 is discussed in national guidance documents.[5]

Use of CIs during routine monitoring

Sterilizer manufacturers will specify the loads which can be sterilized in each cycle programmed into the equipment and medical device manufacturers and will specify which types of sterilization process can be used to sterilize their

products. It is important that these instructions are followed. However, despite best intentions, in a busy sterile processing department it is possible to inadvertently process a device or load in a sterilization cycle which is not recommended by the manufacturer. It is also possible to use inappropriate accessory items and sterile barrier systems, which can, individually or in combination compromise process efficacy.[9] The placement of type 4 VH_2O_2 CIs at locations within a pack identified during PQ will ensure that the end user can see that sterilizing conditions were met at the point(s) of placement and therefore aid in answering the question "is the sterility of the pack confirmed?", as discussed in the WHO surgical safety checklist.[6]

The value of reference colors – a warning

The interpretation of color change of CIs is subjective and depends on human factors such as the experience, health, visual acuity, or stress levels of the operator, and environmental factors such as the brightness of incident light.[10] The presence of a color reference, either printed on the CI or in instructions, might aid or confuse interpretation, if not a good match for the pass color. CIs placed inside sterile packs will be interpreted by practitioners who are under pressure to use the instruments and might be in subdued light, so many indicators exhibiting marginal fails might be interpreted as passes. CIs with a clear color change, which are easily interpretable under less than ideal conditions, are therefore more valuable than others which do not. It is essential that manufacturers provide comprehensive educational and training material not only for SPD staff but also for the practitioners (e.g. Operating Room staff) who will interpret the color change at the point of use.

Summary

CIs form part of an overall quality assurance system, which when taken as a whole, provides assurance that each and every pack is sterile. The use of chemical indicators of good quality in terms of performance and ease of interpretation is vital in order to make meaningful judgements. HPN

References:

1. Submission and Review of Sterility Information in Premarket Notification (510(k) Submissions for Devices Labelled as Sterile. Guidance for Industry and Food and Drug Administration Staff, January 21 2016, Food and Drug Administration, Washington, USA

2. Wallace, C, Breaking the Chain of Infection, Self-Study Series, Healthcare Purchasing News, October, 44-47, 2020.

3. EN ISO 11138 Sterilization of health care products - Biological indicators - Part 1: General requirements, 2017,

4. EN ISO 11140-1, Sterilization of health care products - Chemical indicators - Part 1: General requirements, 2014

5. ANSI/AAMI ST 58.:2013 Chemical sterilization and high-level disinfection in health care facilities , 2013, Association for the Advancement of Medical Instrumentation.

6. World Health Organization, WHO surgical safety checklist, 2009.

7. Kirk, B. Evaluation of a number of chemical indicators for monitoring vaporized hydrogen peroxide (VH2O2) sterilization processes. Zentr Steril, 2020; 28(4), 208-217

8. Kirk, B. Detecting vaporized hydrogen peroxide sterilization (VH2O2) process failures in clinical settings using chemical indicators. Zentr Steril, 2020; 28(6): 334-343.

9. Talapa, L, Vaporised Hydrogen Peroxide VH2O2 Sterilization; riding atop a new wave, presentation at IAHCSMM 2019 annual conference April 27th to May 1st, Anaheim, CA2019.

10. Hurlbert A, Pearce B, Aston S. All illuminations are not created equal: The limits of color constancy. *In: 38th European Conference on Visual Perception (ECVP).* 2015, Liverpool, UK: Sage Publications Ltd.

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Test Condition	Type 1 CIs		Type 4 CIs	
	Pass	Fail	Pass	Fail
H_2O_2 vapor conc mg/L (tolerance)	2.3 (+/- 0.4)	2.3 (+/-0.4)	SV eg 2.3	SV -20% 1.84
Temperature ºC (tolerance)	50 (+/- 0.5)	50(+/-0.5)	SV eg 50	SV-3 47
Time seconds (tolerance)	360 (+/-1)	7 (+/-1)	SV eg 360	SV-25% 270

Table 3: The exposure conditions for a pass and fail response for a type 1 and 4 VH_2O_2 CI according to EN ISO 11140-1.

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Current evidence

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Circle the one correct answer:

1 Steam Sterilization is the most popular method used in hospitals.
A. True
B. False

2 Which is the most recently introduced low temperature sterilization process now popular in hospitals?
A. EO
B. Irradiation
C. Vaporized hydrogen peroxide sterilization

3 Validation of a sterilizer involves three steps.
A. True
B. False

4 Which type of indicator provides microbiological assurance of process efficacy?
A. Physical indicators
B. Biological indicators
C. Chemical indicators

5 How many types of chemical indicators are there?
A. 4
B. 5
C. 6

6 Type 1 chemical indicators are internal pack indicators for placement inside instrument sets.
A. True
B. False

7 For a vaporized hydrogen peroxide sterilization process to be effective, the correct time and concentration of hydrogen peroxide are the only two considerations.
A. True
B. False

8 A type 1 chemical indicator must show a pass when exposed to:
A. 2.3mg/L VH_2O_2 at 50oC for 360 seconds
B. 3.2mg/L VH_2O_2 at 50oC for 360 seconds
C. 2.3mg/L VH_2O_2 at 50oC for 7 seconds

9 EN ISO 11140-1 specifies requirements for types 4, 5 and 6 VH_2O_2 chemical indicators.
A. True
B. False

10 The stated values for a chemical indicator specify the conditions under which it will show a fail result.
A. True
B. False

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